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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,395	04/03/2001	Paul G. Alchas	P-4498C1	2608
26253 7590 02/07/2008 DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880				
			EXAMINER MENDEZ, MANUEL A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/825,395

Applicant(s)

ALCHAS, PAUL G.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,25-34 and 36-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,25-34 and 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 25-34, and 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Linder, Hjertman et al., or Kling in view of Japanese Publication No. 2000-37456 or WO 99/34850**. The applicant has amended the independent claims of this application with claim language disclosing that the limiter portion is proximate to the needle and non-movable with respect to the hub portion.

In relation to the term "proximate", the specification does not provide a definition of this term. However, the dictionary defines this term as "very near or next, as in space, time, or order". Based on the cited extrinsic evidence, **Linder, Hjertman et al., and Kling** disclose apparatuses with limiter portions that are located proximate to the needle.

Additionally, concerning the term "non-movable", the same references disclose apparatuses that are non-movable at the time when the needle penetrates the skin of a patient. It is important to recognize that the criticality of the cited inventions is that the disclosed apparatuses allow the needle to penetrate the skin only at a pre-selected depth. Certainly, these apparatuses

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could not function properly if the limiter moved at the time of injection.

Importantly, these apparatuses not only disclose a non-movable limiter at the time of needle penetration, but also an apparatus that allows the operator to pre-select the depth of insertion of needle. Based on these observations, **Linder, Hjertman et al., and Kling** disclose apparatuses having limiters that are non-movable at the time the needle penetrates the skin.

In order to eliminate any questions concerning the "non-movable" issue, **Japanese Publication No. 2000-37456 and WO 99/34850** disclose structures that only offer one pre-selected depth for needle insertion. Accordingly, based on this evidence, for a person of ordinary skill in the art, modifying the apparatuses disclosed by **Linder, Hjertman et al., or Kling** with a limiter having only one pre-selected depth for needle insertion, would have been considered obvious in view of the proven conventionality of this limiter design.

Response to Arguments

Applicant's arguments filed 10/19/2007 have been fully considered but they are not persuasive. The amendment to the pending claims disclosing a "preselected distance which is set during the manufacture of the intradermal delivery device" does not overcome the pending rejections. It is noted for the record that for a person of ordinary skill in the art, designing a device to a preselected distance during manufacture would have been considered obvious since the cited references suggest that it is a design choice to either design a delivery device with an adjustable limiter or with a limiter having a preselected distance from the skin that is set during manufacture. Moreover, a person of

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ordinary skill in the art that has a delivery device with an adjustable limiter, but uses the delivery device constantly for infusion at one particular distance, would have recognized that it would be safer to modify the design to have one particular distance in order to prevent accidental injections at undesired distances.

Therefore, amending the claim to suggest preselection of the distance during manufacture is not sufficient to overcome the pending rejections.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner respectfully requests application to review the following patents: (1) Riethmueller, (2) Son, and (3) Carson et al.

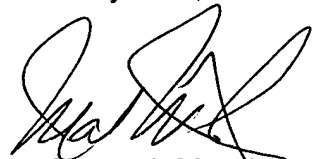
Additionally, since the status of claims 38-47 was not addressed in the last office action, this action is not a final rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Manuel Mendez
Primary Examiner
Art Unit 3763

MM